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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,761	09/15/2003	J. Christopher Flaherty	59249-157 (INSL-125DV)	1492
36310	7590	12/26/2007		
INSULET CORPORATION 9 Oak Park Drive Bedford, MA 01730			EXAMINER MACNEILL, ELIZABETH	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 12/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/662,761	<b>Applicant(s)</b> FLAHERTY ET AL.	
	<b>Examiner</b> Elizabeth R. MacNeill	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31-79,82 and 83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-79,82 and 83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 October 2007 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 31-34, 40-42, 46, 47, 59-61, 64-67, and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US 5,622,482).

Lee teaches a fluid delivery device capable of delivering fluid to a patient comprising

an exit port assembly (24) with outlet and check valve (26)

a dispenser (100) including a container (30), an inlet (20) and check valve (22), a side wall (30), and

a plunger assembly received wholly within the container (Fig 2) including

a first lateral segment (38), a second lateral segment (40), and a shape memory element (50) connecting the first and second lateral segments. See operation in Figs 3-4.

As to claim 32, see titan-nickel alloy Col 1 line 38.

As to claims 33, 34, 40, 42, 59, 65, 78 see Fig 2-4.

As to claim 41, 64 the plunger assembly is prevented from rotating since the shape memory wire is connected on the sides of the plunger (at pins 42). See Figs 3-4.

As to claim 60, 61 see spring 44.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 35, 37-39, 62, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee as applied to claims 31 and 61 above, and further in view of Tabei et al (US 4,899,910).

Tabei teaches a syringe injector with first (3) and second (6) lateral segments held apart by a rigid projection (extending from 3) and biased apart by a shape memory spring (8). See Fig 5 and 6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the rigid projection and coiled spring shape with the plunger assembly of Lee in order to prevent the shape memory element from contracting too

much and causing the first and second lateral segments to be disposed too close together. It has also been held that modifying similar devices in the same way is within the skill of an ordinary worker in the art.

6. Claims 49-55, 79 and 69-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee as applied to claims 31 and 61 above, and further in view of Siposs et al (US 4,435,173).

Lee teaches a fluid pump without an associated fluid delivery system (i.e. an insulin pump).

Siposs teaches a fluid delivery system for use which a syringe type pump (Fig 1). The fluid delivery system includes a reservoir (24) of insulin (see Abstract), patient needle (22), a local processor (64), power supply (52), and housing (10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the plunger assembly of Lee with the fluid delivery system of Siposs in order to deliver insulin to a patient in a controlled manner.

7. Claims 56, 57, 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee as applied to claims 31 and 61 above, and further in view of Tune et al (US 5,630,710).

Lee does not teach a wireless receiver and remote for control of his fluid pump.

Tune teaches a well-known system of using a remote control and wireless receiver to program an infusion pump. See Abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the remote control of Tune with the pump of Lee in order to

allow a physician or other health care worker to adjust the fluid delivery parameters without disturbing the patient.

8. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee as applied to claim 31 above, and further in view of Ingram (US 5,836,066).

Lee does not teach a cooling element for use with the shape memory alloy.

Ingram devices a shape memory alloy with a heat sink or other cooler. (Fig 16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the cooler of Ingram in order to accurately control the restoration of the shape memory alloy of Lee.

9. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee as applied to claim 1 above, and further in view of Wapner et al (US 6,059,001).

Lee does not teach that the shape memory element is a collapsible bellows.

Wapner teaches that it is known in the art to modify a shape memory element into a bellows (Fig 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the bellows of Wapner since it is a function equivalent of the shape memory wire of Lee and simple substitution is within the skill of ordinary worker in the art.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 48, 58, 68, 82 and 83 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 21 and 22 of U.S. Patent No. 6,723,072. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 requires all the elements of claim 58 and claims 21 and 22 are equivalent to claims 58/82 and 68/83. In the '072 patent the applicant elected Fig 17 which is the only figure showing the "strut" of claims 58/82 and 68/83.

### ***Response to Arguments***

12. Applicant's arguments with respect to claims 31-79, 82 and 83 have been considered but are moot in view of the new ground(s) of rejection.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM



KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

